Remarks

I. Introduction

With the addition of new claims 22 to 31, claims 1 to 31 are pending in the present application. In view of the foregoing amendment, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Objection to Claims 4 to 11 and 15 to 21

Claims 4 to 11 and 15 to 21 were objected to as depending from multiple dependent claims. Applicants have amended the claims and added new claims 22 to 31 such that no multiple dependent claim depends from another multiple dependent claim.

III. Rejection of Claims 1 to 3 and 12 to 14 Under 35 U.S.C. §102(e)

Claims 1 to 3 and 12 to 14 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,110,384 ("Goux et al."). Applicant respectfully submits these claims are not anticipated by Goux et al. and requests that the §102(e) rejections be withdrawn.

Claim 1 relates to a method for determining the distribution volume of a blood component in the body of an organism during an extracorporeal blood treatment, in which the blood to be treated flows in an extracorporeal circuit through the blood chamber of a dialyzer subdivided by a semipermeable membrane into the blood chamber and a dialyzing-fluid chamber, and dialyzing fluid flows in a dialyzing-fluid path through the dialyzing-fluid chamber of the dialyzer. Claim 1 recites that the method includes the step of bringing about a change in the concentration of a blood component in the blood upstream of the dialyzer by a change in a physical or chemical characteristic in the dialyzing fluid upstream of the dialyzer. Claim 1 recites that the method also includes the step of measuring the change in the physical or chemical characteristic in the dialyzing fluid downstream of the dialyzer which can be attributed to the change in the concentration of the blood component in the blood. Claim 1 recites that the method further includes the step of determining the distribution volume V of the blood component from the change in the physical or chemical characteristic in the dialyzing fluid upstream and

downstream of the dialyzer.

Claim 2 relates to a method for determining the distribution volume of a blood component in the body of an organism during an extracorporeal blood treatment, in which the blood to be treated flows in an extracorporeal circuit through the blood chamber of a dialyzer subdivided by a semipermeable membrane into the blood chamber and a dialyzing-fluid chamber, and dialyzing fluid flows in a dialyzing-fluid path through the dialyzing-fluid chamber of the dialyzer. Claim 2 recites that a physical or chemical characteristic of the dialyzing fluid is altered in the dialyzing-fluid path upstream of the dialyzer, and the physical or chemical characteristic of the dialyzing fluid is measured downstream of the dialyzer. Claim 2 recites that the change as a function of time in the concentration of a blood component in the blood upstream of the dialyzer Δcbi is determined from the physical or chemical characteristic of the dialyzing fluid upstream and downstream of the dialyzer. Claim 2 recites that the distribution volume V of the blood component is determined from the change as a function of time in the concentration of a blood component in the blood.

Claim 12 relates to an apparatus for determining the distribution volume of a blood component in the body of an organism during an extracorporeal blood treatment in conjunction with an extracorporeal blood-treatment device, in which the blood to be treated flows in an extracorporeal circuit through the blood chamber of a dialyzer subdivided by a semipermeable membrane into the blood chamber and a dialyzing-fluid chamber, and dialyzing fluid flows in a dialyzing-fluid path through the dialyzing-fluid chamber of the dialyzer. Claim 12 recites that the apparatus includes a device for altering the physical or chemical characteristic of the dialyzing fluid in the dialyzing-fluid path upstream of the dialyzer. Claim 12 recites that the apparatus includes a measuring device for determining the physical or chemical characteristic of the dialyzing fluid in the dialyzing-fluid path downstream of the dialyzer. Claim 12 recites that the apparatus includes an arithmetic and evaluation unit which is designed in such a way that the distribution volume V of the blood component can be determined from a change in the physical or chemical characteristic in the dialyzing fluid downstream of the dialyzer which can be attributed to the change in the concentration of a blood component in the blood because of a change in the physical or chemical characteristic in the dialyzing fluid upstream of the dialyzer.

Claim 13 relates to an apparatus for determining the distribution volume of a blood component in the body of an organism during an extracorporeal blood treatment in conjunction with an extracorporeal blood-treatment device, in which the blood to be treated flows in an extracorporeal circuit through the blood chamber of a dialyzer subdivided by a semipermeable membrane into the blood chamber and a dialyzing-fluid chamber, and dialyzing fluid flows in a dialyzing-fluid path through the dialyzing-fluid chamber of the dialyzer. Claim 13 recites that the apparatus includes a device for altering the physical or chemical characteristic of the dialyzing fluid in the dialyzing-fluid path upstream of the dialyzer. Claim 13 recites that the apparatus includes a measuring device for determining the physical or chemical characteristic of the dialyzing fluid in the dialyzing-fluid path downstream of the dialyzer. Claim 13 also recites that the apparatus includes an arithmetic and evaluation unit which is designed in such a way that the change as a function of time in the concentration of the blood component Δcbi in the blood upstream of the dialyzer can be determined from the physical or chemical characteristic of the dialyzing fluid upstream and downstream of the dialyzer, and the distribution volume V of the blood component can be determined from the change as a function of time in the concentration of the blood component upstream of the dialyzer.

Goux et al. purport to disclose a method for determining a parameter - D (dialysance), K (clearance), Kt/v (clearance multiplied by treatment time and divided by the volume of distribution of urea), Cbin (concentration of sodium in a patient's bloodstream upstream of a hemodialyser) - indicative of the effectiveness of an extracorporeal blood treatment carried out using a membrane exchanger. Goux et al. state that the method includes the steps of flowing through the exchanger a treatment liquid having a concentration characteristic (Cd) and of varying the value of the characteristic (Cd) upstream of the exchanger for a time at the end of which the characteristic (Cd) is returned to a nominal value. Goux et al. also state that a plurality of values adopted by the characteristic (Cd) downstream of the exchanger in response to the upstream variation is measured and stored in memory. Goux et al. also state that the area (Sout) of a downstream perturbation region is determined, which is bounded by a baseline and a curve representing the variation of the measured values with respect to time. Furthermore, Goux et al. state that the parameter (D, K, Kt/v, Cbin) indicative of the effectiveness of the treatment is calculated using the area (Sin) beneath the upstream curve and an area beneath

a downstream curve.

The Office Action states that "Goux discloses a method of determining a parameter of extracorporeal blood treatment that includes the steps claimed by applicant." Office Action at page 2. The Office Action states that "[i]n particular, Goux discloses that the blood flows through one side of the dialyzer loop, with treatment fluid through the second side of the loop." Office Action at pages 2 to 3. The Office Action states that "[w]hile the treatment fluid flows through the treatment side of the loop, the operator varies the value of a component in stream of treatment fluid upstream of the dialyzer, measuring the value of the component downstream of the dialyzer, and calculating the parameter indicative of the treatment." Office Action at page 3. The Office Action states that "[s]uch a calculation may include a calculation of a substance in the patient's blood [,s]ee columns 2-4." Office Action at page 3. The Office Action states that "[t]he system comprises a conductivity sensors 23 and 25 both upstream and downstream of the dialyzer for taking measurements, a syringe driver for altering the characteristic of the dialyzing fluid, and a computing and control unit 3." Office Action at page 3.

To anticipate a claim, the reference must disclose each and every element of the claimed invention. Verdergaal Bros. v. Union Oil Co. of Cal., 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986).

Applicants respectfully contend that claims 1, 2, 12 and 13 are not anticipated by Goux et al. for at least the reason that Goux et al. do not disclose each and every element of claims 1, 2, 12 and 13. For instance, Goux et al. fail to disclose or even suggest an apparatus or method for determining the distribution volume of a blood component in the body of an organism during an extracorporeal blood treatment, as recited in claims 1, 2, 12 and 13, respectively. Instead, Goux et al. purports to "provide[ ] a method of determining a parameter (D, K, Kt/v, Cbin) indicative of the effectiveness of an extracorporeal treatment of blood." Column 2,

lines 50 to 53. None of the parameters determined by Goux et al., i.e., D (dialysance), K (clearance), Kt/v (clearance multiplied by treatment time and divided by the volume of distribution of urea) and Cbin (concentration of sodium in a patient's bloodstream upstream of a hemodialyser), constitute the distribution volume of a blood component in the body of an organism during an extracorporeal blood treatment. To the extent that the determination in Goux et al. of the parameter Kt/v includes the volume of distribution of urea (v), Goux et al. provide no teaching or suggestion regarding how to actually determine the volume of distribution of urea (v) in the body of an organism during an extracorporeal blood treatment, since it is the clearance K that is determined by the process of Goux et al.

Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

Thus, for at least this reason, Goux et al. fail to teach each and every feature of the claims 1, 2, 12 and 13, and the rejection of claims 1, 2, 12 and 13 should be withdrawn. In addition, claims 3 and 14, which depend from claims 1 and 12, respectively, should be deemed allowable for at least the same reason, and the rejection of these claims should be withdrawn also.

IV. Fees

Any additional fees or charges required at this time in connection with this application may be charged to Patent and Trademarks Office Deposit Account No. 11-0600.

V. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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